



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

October 22, 2007

MEMORANDUM

Subject: Results from Antimicrobial Testing Program

From: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Adam Heyward, PM-34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Product: Lysol Toilet Bowl Cleaner,
EPA Reg. No. 777-81

Formulation From Label:

<u>Active Ingredient(s)</u>	<u>% by wt</u>
Hydrogen Chloride	9.5

On February 15, 2005, this product was tested for hospital disinfectant product performance as part of the Antimicrobial Testing Program (ATP). The product was tested at a 1:25 dilution in sterile tap water (with water hardness between 105 - 115 ppm). 5% horse serum was added as the organic soil load. The product was tested at a contact time of ten minutes at room temperature (20° C). As a result of this testing, Lysol Toilet Bowl Cleaner failed to demonstrate effectiveness against *Staphylococcus aureus*. The failure rate was 22 carriers out of 60 tested. The label of the sample that was tested did not bear a claim for effectiveness against *Staphylococcus aureus*. Therefore, in lieu of enforcement action, this product is being referred to you for regulatory action.

The registrant for this product may use one of the following actions to resolve this failure:

1. The applicant may remove the label claim for effectiveness against *Staphylococcus aureus* from their registration. Under this option, the product no longer qualifies for a label claim as a broad-spectrum disinfectant or a hospital disinfectant. In addition to removing the claim against *Staphylococcus aureus*, all gram positive bacteria, viral, tuberculocidal, and fungal (if present) claims must be removed from the label. The applicant should consult with the Agency prior to using this option.

2. The applicant may reformulate and retest their product to retain the label claim for effectiveness as a broad-spectrum or hospital disinfectant. This testing must be conducted on three batches of product, with 60 carriers per batch, using the AOAC Use-Dilution Method.

If you have any questions regarding this referral, please feel free to contact me.